

FOOD PROCESS FILING FOR ALL METHODS EXCEPT LOW-ACID ASEPTIC**A. PRODUCT**

Name, Form or Style, and Packing Medium: _____

Raw pH: ____ • ____

Governing Regulation:

☐ low-acid (21 CFR 108.35/113)☐ acidified (21 CFR 108.25/114)

Type of Submission:

☐ new☐ replaces ____ — ____ — ____ / ____ — ____☐ cancels ____ — ____ — ____ / ____ — ____

Process Use:

☐ scheduled☐ alternate for ____ — ____ — ____ / ____ — ____☐ emergency for ____ — ____ — ____ / ____ — ____

See OMB Statement on back of page.

FCE

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Y Y M M D D S S S

SID

B. PROCESSING METHOD

NAME OF STERILIZER (MFR. & TYPE) _____

HEATING MEDIUM (e.g., Steam, water, immersion or spray, steam-air) _____

1. ☐ Stilla. ☐ Horizontal b. ☐ Vertical
Divider Plates (complete for a. or b.)☐ None☐ Solid ☐ Perforatedc. ☐ Crateless

Bottom Surface (complete for c.)

☐ Solid ☐ Perforated2. ☐ Agitatinga. ☐ End over End
☐ Axialb. ☐ Continuous☐ Batch3. ☐ Hydrostatic☐ Inner Chain only☐ Outer Chain only☐ Both Inner and
Outer Chain☐ Single Chain☐ Multiple Chain4. ☐ Flame5. ☐ Other (explain)6. ☐ Acidified

Maximum Equilibrium pH: ____ • ____

Method of Acidification: _____

Concentration: ____ • ____

Acidifying Agent: _____

Pasteurization Method: _____

Preservative Used: _____

Concentration: ____ • ____ / ____ • ____ / ____ • ____

CONTAINER TYPE:1. ☐ Tinplate/Steel Can☐ 2-piece☐ Welded2. ☐ Aluminum Can☐ 3-piece☐ Soldered☐ Cemented3. ☐ Glass or Ceramic4. ☐ Flexible Pouch (specify material): _____5. ☐ Semirigid (specify material): Lid _____ Body _____

Seal Method _____

6. ☐ Other (specify): _____**PROCESS ESTABLISHMENT SOURCE** (Limit entry to 30 characters)**DATE LAST ESTABLISHED****PROCESS RECOMMENDATIONS ATTACHED?**☐ YES☐ NO**C. CRITICAL FACTORS: AS DILINEATED BY PROCESS AUTHORITY TO ASSURE COMMERCIAL STERILITY** (Check or Describe)None of the following NO ☐Maximum Water Activity (a_w) MW ☐ (• ____)

Consistency / Viscosity CV

Value (____ • ____)

Units _____

Method Name _____

Temperature (____ • ____)

Container Position in Retort CP ☐Nesting of Containers NC ☐

Fill Method (check applicable method) FM

Hand or Volumetric ☐Vibrating or Tumble ☐Other (specify) ☐% Solids SO ☐ (____ • ____)Solid to Liquid Ratio (wt. to wt.) SL ☐ (____ • ____)Drained wt./Net wt. Ratio DW ☐ (____ • ____)Arrangements of Pieces in Container AP ☐Formulation Changes FC ☐Preparation Method PM ☐Product Quality PQ ☐Matting Tendency MT ☐Layer Pack LP ☐Max. Flexible Pouch/Semirigid Container Thickness in Retort MP ☐ (____ • ____)Max. Residual Air (Flexible Pouch/Semirigid Container) MR ☐ (____ • ____) c.c.Particle Size PS ☐Syrup Strength SS ☐ (____ • ____)Starch Added SA ☐

Max. % (____ • ____)

Type _____

Other Binder OB ☐Min. % Moisture of Dry Ingredients MM ☐ (____ • ____)Other (specify) OT ☐

FCE: _____ SID: _____

COMMENTS: _____ _____ _____		FOR FDA USE ONLY
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Division of HACCP Programs
Regulatory Food Processing and Technology Branch
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